JUL - 6 2004

K032905
Page 1 of 1

Summary of Safety and Effectiveness

Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758
512-834-6237

Trade Name: 3DKnee™ Porous Coated Femoral Component

Common Name: Porous Coated Femoral Component

Classification Name: Knee joint patellofemoraotibial metal/polymer porous coated uncemented prosthesis per 21 CFR888.3565.

Indications:
This device is part of a total knee replacement system utilized in treating patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function. This device is for uncemented use only.

Description:
The 3DKnee™ porous coated femoral component is manufactured from CoCr alloy conforming to ASTM F75. The inner surface is porous coated with CoCrMo beads (ASTM F75) to provide a porous surface for enhanced fixation. It is available in 7 sizes (2-12) and is provided in left and right configurations. The femoral component is designed to match the condyles of the tibial insert for greater congruency and is the same design as the 3DKnee™ cleared in K020114.

Substantial Equivalence
The 3DKnee™ porous femoral component is similar in design, materials and indications to the 3DKnee™ (K020114).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 6 2004

Ms. Debbie De Los Santos
Supervisor, Regulatory/Clinical Services
Encore Medical, L.P.
9800 Metric Boulevard
Austin, Texas 78758

Re: K032905
Trade/Device Name: 3DKnee Porous Coated Femoral Component
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: September 12, 2003
Received: September 22, 2003

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html .

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K032905

Device Name: 3DKnee™ Porous Coated Femoral Component

Indications For Use:

3DKnee™ Porous Coated Femoral Component
Indications For Use

This device is part of a total knee replacement system utilized in treating patients who are candidates for primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

- Noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis
- Avascular necrosis of the femoral condyle
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus or flexion deformities
- Rheumatoid arthritis
- Treatment of fractures that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K032905

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)